ANGIOKARD
Medizintechnik GmbH
an AR Company

ANGIOKARD Medizintechnik GmbH [redacted]

[redacted]

Safety notice - Recall

[redacted]

Friedeburg, 26.02.2024

Urgent safety notice (product recall)

Dear,

today we have to inform you about the following precautionary product recall:

affectes products	Angiokard - articles containing or fitted with a 1-way stopcock which cannot be reliably connected via an LL connection despite the screw cap REF. no. see appendix 1
batch(es) concerned	see appendix 1
AK reference no.	2024-01
cause of FSN	male side of the 1-way valve cannot be securely connected
explanation	via a customer complaint has made us aware that the 1-way valve cannot be reliably and securely connected to other components via the LL connections
expected risk / damage	delay or termination of operations

This results in the following measures for you:

- no longer use the affected product(s)
- return products from your stock
- inform all affected persons (users, customers, etc.)
- fill out the confirmation form and return it

We thank you in advance for your cooperation and ask for your understanding.

With kind regards

Angiokard Medizintechnik GmbH

i.V.

[redacted]

Attachment:

1) confirmation dorm
2) list of REF numbers and batches concerned

[redacted]

Appendix 1: Confirmation form

Urgent safety notice (product recall)

affected products:	Angiokard – sets with affected 1-way stopcock
cause for FSN:	male side of the 1-way stopcock is not safe to connect

(by E-Mail with signed PDF to recall@be.irmed.com by 31.03.2024)
*** No refund is possible for later responses**

sender:

Angiokard Medizintechnik GmbH

recipient:

& all users who use the named products

Corrective action: **Please stop using the affected products.**

For confirmation and for your refund, please provide the following information or acknowledgement as a customer, distributor or retailer of the affected product batch(es).

I hereby confirm, that the affected products are no longer in use. In addition, all persons involved (including third parties, if they have been supplied with the affected products) have been informed of this urgent safety notice.

Please check one option:

☐ the affected products have been used up.

☐ the remaining products should be returned. After return, the returned goods will be credited. [including those that have been passed on to third parties]

Date / Signature: _____

Name in Block capitals: _____

Position: _____

Department / Institution: _____

Phone and Email: _____

Please enter the returned products with quantities in the following table:

Appendix 2 Individual customer list with affected REFs and batches

REF (SAP-Nr.)	produkt	batche(s)	quantity *Return* (pcs.)
161156	Angiographieset Radiologie	239181-000 238869-000	